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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,698	08/27/2001	George Jackowski	2132.022	4301
21917	7590	07/06/2005	EXAMINER	
MCHALE & SLAVIN, P.A. 2855 PGA BLVD PALM BEACH GARDENS, FL 33410			COUNTS, GARY W	
			ART UNIT	PAPER NUMBER
			1641	
DATE MAILED: 07/06/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/940,698

Applicant(s)

JACKOWSKI ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,8-15,21-27 and 31-38 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,8-15,21-27 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/25/02 & 7/15/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III, Claims 32-37 in the reply filed on February 14, 2005 is acknowledged.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 32 step (b) recites each of said labeled antibodies binding to one of said marker proteins. However the specification fails to properly disclose this embodiment. On page 29, lines 5-10 of the specification the applicant discloses that the detector antibody binds to marker protein bound to the capture antibody to form a sandwich structure and then a polyclonal goat labeled antibody which binds to the detector antibody is added. The specification does not provide proper antecedent basis for "each of said labeled antibodies binding to one of said marker proteins".

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 32-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 32, lines 12 and 13 are vague and indefinite because it is unclear how each of the labeled antibodies can bind to one of the marker proteins. Does applicant intend that each labeled antibody binds specifically to the corresponding marker protein to be detected or does applicant intend that the labeled antibody can bind all of the marker proteins. Please clarify.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 32-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackowski (CA 2,263,063) in view of Voller (The Enzyme Linked Immunosorbent Assay, Diagnostic Horizons, Vol. 2, No. 1, February 1978, pages 1-7).

Jackowski discloses detecting the presence of at least three markers in a sample. Jackowski teaches that the three markers can be myelin basic protein, beta subunit of the S100 protein, and neuronal specific enolase (pages 7-8). Jackowski teaches determining the presence of the marker by using antibodies specific for each of the markers and detecting immunospecific binding. Jackowski teaches that sandwich assays such as ELISA can be used (page 12). Jackowski teaches using capture antibodies immobilized to solid support and also teaches using detector antibodies. (pages 12-13). Jackowski teaches that the antibodies can be immobilized on the same solid support or one on one solid support and at least another of the antibodies is immobilized on a second solid support (see claims 14-16). Jackowski teaches control samples (means for comparing) (pages 6, 14 and 24) used to compare with the tested sample. Jackowski teaches the packaging of reagents and components into a kit (p. 1 and claims 14-20). Jackowski teaches including an additional reagent for determining an additional marker (p. 10).

Jackowski differs from the instant invention in failing to specifically teach each of the labeled antibodies binding to one of said marker proteins.

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Voller teach ELIZA formats for detecting an analyte of interest. Voller teaches sandwich assay in which the detection antibodies directly bind to the analyte (see figure 2, page 2). Voller teaches that this provides the advantages of low cost and suitability for use by small diagnostic laboratories (p. 1).

It would have been obvious to one of ordinary skill in the art to incorporate labeled antibodies as taught by Voller into the method of Jackowski because Jackowski teaches that any suitable immunoassay method may be utilized, including those which are commercially available, to determine the level of each of the specific markers (p. 12) and further because Voller teaches that this provides the advantages of low cost and suitability for use by small diagnostic laboratories. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating labeled antibodies that specifically bind to the analyte of interest in the method of Jackowski.

Conclusion

9. No claims are allowed.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Jackowski (WO 00/52476) disclose for determining if a subject has had a stroke and, if so, the type of stroke which includes analyzing the subject's body fluid for at least four markers of stroke, myelin basic protein, S100 protein, neuronal specific enolase and a brain endothelial membrane protein.

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Valkirs et al (US 2003/0119064) disclose methods and kits for diagnosing and evaluation of stroke and transient ischemic attacks. Valkirs et al disclose determining one or more specific markers of stroke.

Janigro et al (US 6,884,591) disclose kits for determining S100 and NSE in samples (abstract and col 4).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts
Examiner
Art Unit 1641
June 27, 2005



LONG V. LE
SUPERVISORY PATENT EXAMINER
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06/28/05